## The Department of Health and Human Services Meeting of the

# Secretary's Advisory Committee on Human Research Protections (SACHRP) Tuesday, February 28, 2012 – Wednesday, February 29, 2012 Hubert H. Humphrey Building, Room 705A FINAL AGENDA

### Tuesday, February 28, 2012

Tuesday, February 28, 2012	
8:30 am – 8:45 am	Welcome: Opening Remarks Barbara Bierer, M.D. SACHRP Chair
	Jerry Menikoff, M.D., J.D. Director, OHRP
8:45 am – 10:15 am	Presidential Commission for the Study of Bioethical Issues: Moral Science: Protecting Participants in Human Subjects Research COL Nelson Michael, M.D., Ph.D. Director, Division of Retrovirology Walter Reed Army Institute of Research (WRAIR)
10:15 am – 10:30 am	BREAK
10:30 am – 11:30 pm	Summary of Public Comment: Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators Edward Bartlett, Ph.D., OHRP
11:30 am – 12:00 pm	Discussion
12:00 pm – 1:00 pm	LUNCH
1:00 pm – 3:00 pm	Subpart A Subcommittee (SAS) Daniel K. Nelson, M.S., CIP, SAS Co-chair David Borasky, M.P.H., CIP, SAS Co-chair
3:00 pm – 3:15 pm	BREAK
3:15 pm – 4:45 pm	Discussion
4:45 pm – 5:00 pm	<b>Public Comment</b>
5:00 pm – 5:15 pm	Wrap-up Discussion and Adjourn

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#### Wednesday, February 29, 2012

8:30 am – 8:45 am **Opening Remarks** 

Barbara Bierer, M.D. SACHRP Chair

Jerry Menikoff, M.D., J.D.,

Director, OHRP

8:45 am- 10:30 am **Subcommittee on Harmonization (SOH):** 

David Forster, J.D., SOH Co-chair Mark Barnes, J.D., SOH Co-chair

10:30 am – 10:45 pm **Break** 

10:45 am- 12:30 pm Discussion

12:30 pm- 1:30 pm LUNCH

1:30 pm – 3:45 pm **Re-examining Component Analysis** 

David Forster, J.D., SOH Co-chair Vice President, Office of Compliance Western International Review Board

Robert J. Levine, M.D.

Professor of Medicine and Lecturer in Pharmacology Chair: Executive Committee, Interdisciplinary Center

for Bioethics Yale University

Robert "Skip" Nelson, M.D., Ph.D.

Senior Pediatric Ethicist, Office of Pediatric

Therapeutics

Food and Drug Administration

3:45 pm - 4:00 pm **Public Comment** 

4:00 pm – 4:15 pm Wrap-up Discussion and Adjourn